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29 October 2009

(54) **Title:** FLOW ELEMENTS FOR USE WITH FLEXIBLE SPINAL NEEDLES, NEEDLE ASSEMBLIES AND METHODS  
FOR MANUFACTURE AND USE THEREOF

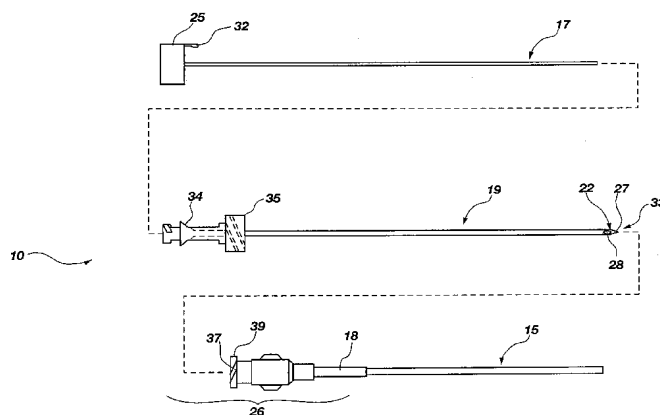


FIG. 1

(57) **Abstract:** A flow element (50) for use with flexible needles and flexible needle assemblies (10) to minimize flow occlusion within a flexible needle (15) is provided. The flow element (50) is particularly suited for uses with a flexible needle (15) for minimizing incidence of post-dural puncture headache. The flow element (50) includes a body having an internal flow path for conducting a fluid through a flexible needle, and an anti-restriction member (56). The anti-restriction member (56) includes an elongated body (58), a proximal end (70) coupled to the body within the internal flow path, and a distal end (60) for positioning at least a portion of the elongated body within a flexible needle. A flexible spinal needle assembly (10) for minimizing flow occlusion through an internal flow path of a flexible needle (15) by unintended kinking that is potentially caused by ligament or muscle layer movements is also provided. In other embodiments, a flexible spinal needle assembly (10), a flexible spinal needle assembly kit, a method for installing a flexible spinal needle assembly, and a process for producing a flow element are provided.

## INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/US2009/000250****A. CLASSIFICATION OF SUBJECT MATTER****A61M 5/178(2006.01)i, A61M 5/32(2006.01)i**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC A61M 5/178, A61B 5/02, A61M 25/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
eKOMPASS (KIPO internal), USPTO, Delphion**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	US 4994036 (Juergen Biscopig et. al.) 19 February 1991 See abstract; figures 1a-7; columns 1-3; and 1-11	13,16,17 1,4-8,24-25 2-3,9-11,14,18
Y	US 3722505 (Alexander Kolin) 27 March 1973 See abstract; figures 1-10; columns 4-10; and claims 1-11	1,4-8,24-25
A	US 2006/116608 A1 (Andrew I Poutiatine et. al.) 01 January 2006 See abstract; figures 1-4; pages 1-4; and claims 1-14	1-11,13-14,16-18 24-25
A	US 2006/129012 A1 (David A. Putz) 15 June 2006 See abstract; figures 1-9; pages 3-5; and claims 1-32	1-11,13-14,16-18 24-25
A	US 5232442 (Mark D. Johnson et. al.) 03 August 1993 See abstract; figures 1-4B; columns 4-8; and claims 1-12	1-11,13-14,16-18 24-25



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

07 SEPTEMBER 2009 (07.09.2009)

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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/US2009/000250**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 04994036 A	19.02.1991	EP 0362494 A1	11.04.1990
US 3722505	27.03.1973	None	
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US 05232442 A	03.08.1993	US 05304141 A	19.04.1994
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**INTERNATIONAL SEARCH REPORT**

International application No.

**PCT/US2009/000250****Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 19-23  
because they relate to subject matter not required to be searched by this Authority, namely:  
The subject-matter of claims 19-23 does not require an international search report with respect to industrial applicability as it is directed to a method for treatment of the human body by therapy or surgery.
2. ☒ Claims Nos.: 12 and 15  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
The subject matter of claims 12 and 15 is not clear because claim 14 relates to the flexible spinal needle assembly and claim 25 relates to the process for producing a flow element, but claim 12 dependent on claim 14 related to the flow element and claim 15 dependent on claim 25 relates to the flexible spinal needle assembly.
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.